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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,791	02/08/2001	Jon A. Wolff	Mirus.006.03	6737

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Mark K. Johnson
P.O. Box 510644
New Berlin, WI 53151-0644

EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 03/12/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/779,791

Applicant(s)
Wolff et al.

Examiner
Joseph Weitach

Art Unit
1632



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 8, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-13 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

This application filed February 8, 2001, is a continuation in part of application 09/312,351, filed May 14, 1999.

Claims 1-13 are pending and currently under examination.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6 and 13, drawn to a compound for inserting into an organism comprising (a) a disulfide bond which is cleaved more rapidly than oxidized glutathione and (b) a transduction signal, classified in class 514, subclass 1, class 536, subclass 23.1, 24.1, depending on the species elected.
- II. Claims 1-6 and 13, drawn to a compound for inserting into an organism comprising (a) a disulfide bond in which one of the constituent thiols has a lower pKa than glutathione and (b) a transduction signal, classified in class 514, subclass 1, class 536, subclass 23.1, 24.1, depending on the species elected.
- III. Claims 1-6 and 13, drawn to a compound for inserting into an organism comprising (a) a disulfide bond which is activated by intramolecular attack from a free thiol and (b) a transduction signal, classified in class 514, subclass 1, class 536, subclass 23.1, 24.1, depending on the species elected.

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- IV. Claims 7-12, drawn to a process for delivering a compound having a labile disulfide bond wherein the compound comprises (a) a disulfide bond which is cleaved more rapidly than oxidized glutathione and (b) a transduction signal, classified in class 514, subclass 1, class 536, subclass 23.1, 24.1, depending on the species elected.
- V. Claims 7-12, drawn to a process for delivering a compound having a labile disulfide bond wherein the compound comprises (a) a disulfide bond in which one of the constituent thiols has a lower pKa than glutathione and (b) a transduction signal, classified in class 514, subclass 1, class 536, subclass 23.1, 24.1, depending on the species elected.
- VI. Claims 7-12, drawn to a process for delivering a compound having a labile disulfide bond wherein the compound comprises (a) a disulfide bond which is activated by intramolecular attack from a free thiol and (b) a transduction signal, classified in class 514, subclass 1, class 536, subclass 23.1, 24.1, depending on the species elected.

Claims 1-6 and 13 are generic to groups I-III and will be examined to the extent they encompass the elected invention. Claims 7-12 are generic to groups IV-VI and will be examined to the extent they encompass the elected invention.

The inventions are distinct, each from the other because of the following reasons:

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Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different compounds comprise different types of disulfide linkages. A disulfide bond which is activated by intramolecular attack from a free thiol does not have to be more rapidly oxidized than oxidized glutathione or be constructed from a constituent thiol having a lower pKa than glutathione. Further, while a constituent thiol may have a lower pKa than glutathione once it is a part of disulfide bond it would not necessarily be cleaved more rapidly than oxidized glutathione. Conversely, a disulfide bond which is cleaved more rapidly than oxidized glutathione does not have to be constructed with a constituent thiol which has a lower pKa than glutathione.

Inventions IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of delivery comprise the use of different compounds which comprise different types of disulfide linkages. A disulfide bond which is activated by intramolecular attack from a free thiol does not have to be more rapidly oxidized than oxidized glutathione or be constructed from a constituent thiol having a lower pKa than glutathione. Further, while a constituent thiol may have a lower pKa than glutathione once it is a part of disulfide bond it would not necessarily be cleaved more rapidly than oxidized glutathione. Conversely, a disulfide bond which is cleaved more rapidly than oxidized glutathione does not have to be constructed with a constituent thiol which has a

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lower pKa than glutathione. In each case, the different disulfide containing compounds are drawn to different starting materials which have different properties would require separate and unique steps of handling and delivery and may have a different affect when administered to a mammal.

Inventions I-III and IV-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compositions can be used in methods for the delivery to cells in culture. Additionally, the process can be practiced with compounds which do not have disulfide bonds or with disulfide bonds with different properties.

In addition, upon election of any one of groups I-VI an election of species is also required. This application contains claims directed to the following patentably distinct species of the claimed invention: transduction signals of (1) Tat, (2) VP22, (3) ANTP, (4) a peptide containing cationic charges/residues and (5) a polynucleotide.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 5, 7 are generic. The remaining dependent claims specifically recite and are drawn to one of the indicated species.

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Further, because these inventions are distinct for the reasons given above and the search required for each on of Group I-VI is not required or coextensive with each other, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach